

No. 89-243

Supreme Court, U.S.

FILED

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IN THE  
**Supreme Court of the United States**

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,  
*Petitioner,*  
v.

MEDTRONIC, INC.,  
*Respondent.*

On Writ of Certiorari to the  
United States Court of Appeals  
for the Federal Circuit

**BRIEF OF AMICI CURIAE  
ZIMMER, INC. AND  
BRISTOL-MYERS SQUIBB COMPANY  
IN SUPPORT OF PETITIONER**

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November 24, 1989

### **QUESTION PRESENTED**

Did the Federal Circuit err as a matter of law by expanding the limited patent infringement exemption found in 35 U.S.C. § 271(e)(1) beyond the two subjects specifically mentioned in that statute, namely "drugs" and "veterinary biological products," to encompass, and thereby to erode patent protection for, medical devices?

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INTEREST OF THE AMICI CURIAE

Zimmer, Inc., a manufacturer of medical devices, and Bristol-Myers Squibb Company, its parent corporation (hereinafter referred to collectively as "Zimmer"), file this brief as *amici curiae* in support of the Petitioner, Eli Lilly and Company ("Lilly"). Lilly seeks reversal of the decision of the Court of Appeals for the Federal Circuit which expanded the limited patent infringement exemption found in 35 U.S.C. § 271(e)(1)<sup>1</sup> beyond the two subjects specifically mentioned in that statute, namely

<sup>1</sup> Section 271(e)(1) was added to the patent laws as part of the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "1984 Act").

"drugs" and "veterinary biological products," to encompass, and thereby to erode patent protection for, medical devices and other nondrug products regulated by the Food and Drug Administration ("FDA"). *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989). This decision, if allowed to stand, will have potentially enormous adverse economic effects on the business of Zimmer and similarly situated manufacturers of medical devices.<sup>2</sup> More importantly, this decision would curtail innovation by all United States manufacturers of medical devices at a time when innovation is greatly needed to address the numerous health care problems of our aging population.

Zimmer respectfully submits that because it is a member of the medical device industry and manufactures patented products potentially affected by the Federal Circuit's decision, yet does not have a direct interest in the specific products being contested, it is in a position to offer a useful perspective to the Court on the question presented.

### SUMMARY OF ARGUMENT<sup>3</sup>

The Federal Circuit's decision is at odds with the plain meaning of Section 271(e) (1) as manifested in the particular words and phrases Congress used for the provision. The decision is also inconsistent with Congress' intent. The legislative history is replete with references to the application of the exemption to drugs, yet contains no references to medical devices. The context in which the statute was enacted, after prolonged negotiations about, *inter alia*, patent infringement provisions, between gen-

<sup>2</sup> The medical device industry is of substantial importance to the United States economy, involving an estimated more than \$24 billion in shipments for 1989, with an international trade surplus estimated at \$1.3 billion. U.S. Dept. of Commerce, *U.S. Industrial Outlook 1989*, 32-1 (1989).

<sup>3</sup> *Amici* adopt the Statement of the Issues and Statement of the Case included in the brief of Petitioner Lilly.

eric *drug* manufacturers and innovator *drug* manufacturers, also confirms Congress' intent to limit the scope of the provision to drugs. Lastly, the Federal Circuit's decision would significantly and unjustifiably expand the statute because of differences in the ways drugs and medical devices are tested and would therefore constitute judicial encroachment on the legislative sphere.

Zimmer requests this Court to restore the plain meaning of the statute by reversing the Federal Circuit's decision and limiting the scope of Section 271(e) (1) to its enumerated subjects—drugs and veterinary biological products.

### ARGUMENT

#### I. THE FEDERAL CIRCUIT'S DECISION IS AT ODDS WITH THE PLAIN MEANING OF THE STATUTE

As recently amended, Section 271(e) (1) states:

It shall not be an act of infringement to make, use or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e) (1).<sup>4</sup>

<sup>4</sup> The last clause of the statute originally referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary biological products" and the last clause in the parenthetical were added by the Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988) ("1988 Amendment").

Congress' decision to amend Section 271(e) (1) to bring certain animal drugs within the ambit of that Section emphasizes the

Courts are bound by a statute's specific language when construing its provisions. *See, e.g., United States v. James*, 478 U.S. 597, 604-05 (1986). Under a straightforward reading of the statutory language, Section 271 (e) (1) grants a narrow exemption from patent infringement in certain circumstances where it is necessary to develop and submit information to obtain FDA approval for drugs and veterinary biological products.<sup>5</sup> The Federal Circuit, however, has read the provision to grant an exemption from patent infringement not only for developing information necessary to obtain approval of drugs and veterinary biological products but also for developing information necessary to obtain approval of medical devices and a wide spectrum of other products.

The Federal Circuit's interpretation requires a strained reading of the plain language of the statute. To bring medical devices within the ambit of the statute, it is necessary to find that the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" is shorthand for the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act of 1944, 42 U.S.C. § 262 (the other statute under which FDA approves some (biological) drugs). It is simply not credible that Congress used such shorthand, when it spelled out "Federal Food, Drug, and Cosmetic Act" and "the Act of March 4, 1913" (the Act regulating veterinary bio-

narrowsness of the original provision. The early legislative history of the 1988 Amendment confirms this interpretation. *See* S. Rep. No. 448, 99th Cong., 2d Sess. at 13 (1986), describing the proposed amendment:

This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. A similar provision applies to human pharmaceuticals. (emphasis added.)

<sup>5</sup> As discussed in Section II, *infra*, both the legislative history of Section 271(e) (1) as enacted in 1984 and the discussions of commentators confirm that this reading is the common one.

logical products)<sup>6</sup> in a parenthetical proviso a few lines earlier in Section 271 (e) (1).<sup>7</sup>

Respondent Medtronic, Inc. has suggested that the use of the term "patented invention" in the first few lines of Section 271(e) (1), rather than "patented drug," clearly signals that Section 271(e) (1) was intended to be applied to medical devices and certain other nondrug products. In fact, the term "patented invention" was used because Section 271(e) (1) applies not only to drug product patents but also to patents for drug compositions and patents for uses of drugs. Thus, the term "patented drug" would have been potentially unclear, whereas the term "patented invention" clearly covers all three types of drug patents. Moreover, the term "patented invention" is the term used in 35 U.S.C. § 271(a), the provision which Section 271 (e) (1) modifies.<sup>8</sup>

Where Congress intended the 1984 Act to apply to both drugs and medical devices, it explicitly said so. For example, Congress stated that the patent term extension provisions of the 1984 Act apply to products subject to a regulatory review period before commercial marketing or use. 35 U.S.C. § 156(a) (4). Congress then explicitly defined such a product as (a) a human drug product or (b) "[a]ny medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act." 35 U.S.C. § 156(f) (1). Had Congress in-

<sup>6</sup> Act of Mar. 4, 1913 ("Virus-Serum-Toxin Act"), Pub. L. No. 62-430, 37 Stat. 832 (1913) (codified as amended at 21 U.S.C. §§ 151-158).

<sup>7</sup> In the next provision of the statute, 35 U.S.C. § 271(e) (2), Congress again referred to the Federal Food, Drug, and Cosmetic Act by its full name, without resorting to shorthand.

<sup>8</sup> Section 271(a) states that "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

tended for Section 271(e)(1) to apply to medical devices, it would have been similarly explicit.

Under a straightforward reading of the statutory language, then, Section 271(e)(1) grants a narrow exemption from patent infringement in certain circumstances where it is necessary to develop and submit information to obtain FDA approval for *drugs* and *veterinary biological products*. It does not grant an exemption for medical devices and other FDA-regulated nondrug products.

## II. THE FEDERAL CIRCUIT'S DECISION IS INCONSISTENT WITH CONGRESS' CLEAR INTENT

Assuming for a moment that the plain meaning of Section 271(e)(1) is not clear, the Federal Circuit's interpretation of that provision nevertheless violates the well-established principle of statutory construction that courts are required to defer to the intent of Congress where doubt exists about the meaning of the words of a statute. *See, e.g., Mackey v. Lanier Collections Agency & Service*, 486 U.S. 825, 108 S. Ct. 2182, 2191 (1988). Courts may not rewrite legislation in accordance with their own conceptions of prudent public policy, even if the policy choices made by the legislature might appear to be parochial or less than even-handed. *See, e.g., United States v. Rutherford*, 442 U.S. 544, 555 (1979). By contrast, the Federal Circuit's decision seems to be based on its own view of possibly applicable policy considerations. *See Eli Lilly*, 872 F.2d at 406 ("No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation.").<sup>9</sup>

<sup>9</sup> In fact, there is a persuasive reason why Congress would make this distinction. *See* discussion, *infra*, in Section III.

The legislative history of Section 271(e)(1) as enacted<sup>10</sup> unambiguously demonstrates that Section 271(e)(1) was intended to apply only to drugs. Evidence of that intent can be gathered in two ways. First and most directly, Congress many times *said* that this provision applied to drugs. No one in the entire legislative process *ever* suggested that it would apply to medical devices or other nondrug products. Second, the negotiation and ultimate structure of the statute demonstrate that Section 271(e)(1) applies only to drugs.

### A. The Direct Legislative Evidence Is Clear and Uncontroverted

The direct legislative evidence clearly indicates that Congress intended that the limited patent infringement exemption apply only to drugs. Two Committee reports were prepared on the 1984 Act, one by the House Committee on Energy and Commerce and one by the House Committee on the Judiciary. The Report of the Committee on Energy and Commerce stated, "The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 45 (1984) (emphasis added). *See also id.* at 15 ("Finally, Title II [which contains what would become Section 271(e)(1)] provides that it is not an act of patent infringement for a *generic drug maker* to import or to test

<sup>10</sup> It is appropriate to look at Congress' intent in 1984 in enacting Section 271(e)(1) because the original statute included both the disputed phrase "a Federal law which regulates the manufacture, use, or sale of drugs" and an explicit reference to the "Federal Food, Drug, and Cosmetic Act." As noted, the 1988 Amendment, which added the phrase "or veterinary biological products," does not change the analysis. To the contrary, that amendment confirms that Congress intended to limit Section 271(e)(1) to two specifically identified products, *i.e.*, drugs and veterinary biological products.

a *patented drug* in preparation for seeking FDA approval if marketing of the *drug* would occur after expiration of the patent.”) (emphasis added).

The Report of the Committee on the Judiciary described Section 271(e)(1) as permitting “a generic manufacturer [to] obtain a supply of a *patented drug product* during the life of the patent and conduct tests using that product.” H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 5 (1984) (emphasis added). The same Report subsequently referred to “provisions of the bill which permit the limited testing of *drugs* while they are on patent in order to assist in the preparation of an *abbreviated new drug application*.” *Id.* at 29. (emphasis added.) See also 130 Cong. Rec. H8708 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (provision will allow generic manufacturer to “obtain a supply of a *patented drug product* during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to the FDA for approval”) (emphasis added); *id.* at H8712 (statement of Rep. Kindness) (“this bill would provide that the *generic drug manufacturers* can start playing around with the *drug* on which the patent is about to expire within a year”) (emphasis added).

A statement made by Rep. Moorhead underscores this point. He criticized Section 271(e)(1) precisely because it differentiated between pharmaceuticals on the one hand and all other types of patented products on the other:

There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other patent holder.

130 Cong. Rec. H9143 (daily ed. Sept. 6, 1984).<sup>11</sup>

<sup>11</sup> Congress’ intent is further elucidated by the *amicus* briefs in support of Lilly’s request for rehearing *en banc* in the Federal Circuit and in support of certiorari filed by Senator Hatch, the principal Senate author of the 1984 legislation, and Representative

The only legislative reference that has been cited to support the Federal Circuit’s decision in fact, on close analysis, confirms the statute’s focus on drugs. The House Report stated that:

The provisions of Section 202 of the bill [*i.e.*, the Section which, when enacted, would become Section 271(e)(1)] have the net effect of reversing the holding of the court in *Roche*.<sup>12</sup>

H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 27 (emphasis added).

The *Roche* court stated that the issue before it was limited to a narrow question, namely whether “the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute[s] a use which, unless licensed, the patent statute makes actionable?” *Roche*, 733 F.2d at 861. It then stated that the district court had “held” that it does not, and reversed that holding. *Id.*

#### B. The Context in Which Section 271(e)(1) Was Passed Demonstrates that It Applies Only to Drugs

The circumstances surrounding enactment of Section 271(e)(1) confirm that the narrow patent infringement exception was intended to be applied solely to drugs. The legislative history of the 1984 Act clearly reveals that Section 271(e)(1) was enacted by Congress as one part of a many-faceted compromise between *generic drug manufacturers* and *innovator drug manufacturers*. See,

Moorhead, a primary floor manager of the bill in the House. Senator Hatch and Representative Moorhead reiterate in their briefs that Section 271(e)(1) was intended to apply only to drugs. Rehearing Brief of Sen. Hatch and Rep. Moorhead at 2; Brief in Support of Petition for Certiorari at 3.

<sup>12</sup> The Report was referring to *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

*e.g.*, 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore) (legislation "has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, . . . [and] the innovators of new drugs").<sup>13</sup>

The 1984 Act was, in fact, a grand compromise in which statutory changes long sought by the two competing drug manufacturing interests and their respective supporters were passed together. The generic manufacturers, for their part, primarily sought an easier route to FDA approval of generic copies of innovator drugs once patent protection for those drugs had ended.

The Federal Food, Drug, and Cosmetic Act, prior to the 1984 Act, required that the generic manufacturer complete expensive and time consuming safety and effectiveness testing before a new drug application for the generic copy could be approved and the drug could be marketed. It was generally believed that the testing requirements did not make scientific sense. If it could be shown that the generic copy produced the same amount of the drug at the site of its action in the body at the same rate, it could be concluded that that drug would be as safe and effective as the innovator drug. Such a showing could be made by "bioequivalence" tests, in which the generic and innovator drugs were administered to a relatively small number of test subjects and blood samples were taken at set intervals and analyzed.

<sup>13</sup> See also the following statements, all of which refer to the statute as a compromise between opposed drug company interests: 130 Cong. Rec. H8707 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (Act is a "carefully crafted compromise"); *id.* (statement of Rep. Waxman) (Act represents a "compromise among divergent and sharply differing interests"); *id.* (statement of Rep. Synar) (Act "comes after a long and hard and arduous compromise").

FDA had, administratively, developed a form of new drug application that dispensed with the need for full safety and effectiveness testing of generic drugs and permitted approval based on bioequivalence testing. FDA refused, however, to make that short form application, called an "abbreviated new drug application" ("ANDA"), available for drugs first approved after 1962. Generic drug companies thus sought legislation to permit use of ANDAs for copies of innovator drugs first approved after 1962.

Because the costs of full safety and effectiveness testing deterred generic companies from seeking approval of copies of innovator drugs first approved after 1962, the pre-1984 law tended to preserve the market monopolies of innovator drugs even after their patents expired. Innovator companies thus stood to lose economically from a change in the law that would permit use of ANDAs for post-1962 drugs.

Innovator companies had, however, their own interest in changing the law applicable to pharmaceuticals. Because they were required to perform lengthy testing of each new product, and then to wait for extended periods, sometimes many years, for FDA approval of their new drug applications after the testing was completed, the effective patent life applicable to their products after approval was often relatively short. Innovator interests sought restoration of patent time lost in the testing and approval process. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 17-18 (1984).

Title I of the 1984 Act provided what the generic companies had sought, *i.e.*, ANDAs for copies of post-1962 innovator drugs. Title II provided patent term restoration for the innovator companies. Each interest, of course, was actively involved in the negotiation of the opposing interest's title. Thus, Title I contains restrictions on the availability of ANDAs. See 21 U.S.C. § 355 (j) (3), (4). Title II contains limitations on length and

availability of patent term restoration. 35 U.S.C. § 156 (a), (c), (g) (4).

As supporters of the two sides negotiated, it became apparent that each also sought changes in the law of patent infringement. The innovator drug companies wanted FDA to be required to delay approval of ANDAs until valid patents applicable to the drugs covered by the ANDAs had expired. They also wanted notice whenever a generic company submitted an ANDA that might infringe a claimed patent. So there would be no question that litigation could begin at the point when an ANDA was filed with FDA, they wanted the act of filing an ANDA with intent to market during the patent period to be patent infringement. They wanted, in effect, an automatic 30-month preliminary injunction against ANDA approval if that infringement led to patent litigation. They wanted an opportunity to sue the generic company for patent infringement before the generic company could seek declaratory judgment and they wanted any declaratory judgment suit to be brought in the defendant's home district. Ultimately, innovator drug company interests obtained all of these concessions. See 21 U.S.C. § 355(j) (4) (B) (ii) (approval delayed until valid patent expires); 21 U.S.C. § 355(j) (2) (B) (notice); 35 U.S.C. § 271(e) (2) (B) (ANDA submission is patent infringement); 21 U.S.C. § 355(j) (4) (B) (iii) (30-month approval delay); 21 U.S.C. § 355(j) (4) (B) (iii) (restrictions on suits for declaratory judgment).<sup>14</sup>

Generic drug interests obtained concessions in exchange: Innovator companies were required to submit

<sup>14</sup> In the 1988 Amendments, each of these changes was applied to animal drugs. See 21 U.S.C. § 360b(c) (2) (D) (ii) (approval delayed until valid patent expires); 21 U.S.C. § 360b(n) (2) (notice); 35 U.S.C. § 271(e) (2) (B) (submission of abbreviated new animal drug application is patent infringement); 21 U.S.C. § 360b(c) (2) (D) (iii) (30-month approval delay); 21 U.S.C. § 360b(c) (2) (D) (iii) (restrictions on suits for declaratory judgment).

and FDA was required to publish information about patents claiming innovator drugs so as to guide generic companies to potential drugs for copying. 21 U.S.C. § 355(b) (1). And under Section 271(e) (1), bioequivalence testing would no longer be considered patent infringement.<sup>15</sup>

None of these changes in the law of patent infringement applied to medical devices.<sup>16</sup> It is simply not credible that Congress, in the midst of a carefully negotiated drug bill, without giving innovator device manufacturers the many concessions that had been made to innovator drug manufacturers, would have significantly undercut patent protection for innovator devices. It is even less credible that Congress would have done so without the prompting of anyone supporting makers of generic copies of medical devices,<sup>17</sup> and that such a significant change in the law could have been made without any opposition from makers of innovator medical devices.<sup>18</sup> Clearly, the Federal Circuit simply misapprehended Congress' intent on this issue.

<sup>15</sup> The same concessions were applied to animal drugs in 1988. See 21 U.S.C. § 360b(b) (1); 35 U.S.C. § 271(e) (1).

<sup>16</sup> There are provisions for FDA approval of certain types of medical devices that are somewhat parallel to the drug approval provisions. (Only so-called "Class III" medical devices require FDA premarket approval. 21 U.S.C. § 360e. See Section III, *infra*.) The 1984 Act did not, however, change the premarket approval requirements for medical devices in any way. The only change in the law applicable to some medical devices was the opportunity for patent term restoration, which also applied to color additives and food additives. 35 U.S.C. § 156(f) (1) (B).

<sup>17</sup> The legislative history does not reflect any participation by proponents of easier market access for generic copies of medical devices in the debate on this statute.

<sup>18</sup> Some innovator drug manufacturers with medical device subsidiaries were involved in the negotiations which led to the patent term restoration provisions of the 1984 Act. Bristol-Myers Squibb Company, Johnson & Johnson, and American Home Products, for example, are companies that have both drug and device subsidiaries. See, e.g., 130 Cong. Rec. S10,504 (daily ed. Aug. 10, 1984) (state-

Prior to the Federal Circuit's ruling, no one read Section 271(e)(1) as extending beyond drugs. In the instant case, both the district court and the Federal Circuit panel which initially denied Medtronic's motion to stay the injunction entered below pending appeal found that Section 271(e)(1) applied only to drugs. The only other court opinion to discuss the issue prior to the decision below stated that "[i]t is also clear that section 271(e)(1) applies only to drugs, not to medical devices." *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories*, 7 U.S.P.Q.2d 1562, 1565 (D. Del. 1988) (dictum).

Similarly, prior to the Federal Circuit decision, no commentator had ever read Section 271(e)(1) to apply to any product other than drugs.<sup>19</sup> To the contrary, several commentators agreed that that provision "is limited to human drugs, and does not include medical devices . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307-08 (1985); accord A. Fox & A. Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984* 178, 187 (1987).

The legislative history of Section 271(e)(1), the circumstances surrounding its enactment, and the subsequent interpretations of the provisions by the judiciary and commentators all confirm that Congress intended for the narrow patent infringement exemption contained

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ment of Sen. Hatch). There is no evidence that these companies expressed any views on the advisability of applying Section 271(e)(1) to medical devices. It is difficult to believe that such a significant effect on medical device innovation would have elicited no reaction from these major device manufacturers.

<sup>19</sup> The 1988 Amendment has of course extended the statute's scope to animal drugs and veterinary biological products.

therein to be limited to drugs. The Federal Circuit's decision misinterprets that intent and should be reversed.

### III. THE FEDERAL CIRCUIT'S DECISION CONSTITUTES JUDICIAL LEGISLATION WITH FAR REACHING RESULTS

The Federal Circuit's decision significantly expands Section 271(e)(1), producing effects never contemplated by Congress because of differences in the way drugs and medical devices are tested and regulated. This case provides a clear illustration of the dangers of judicial usurpation of Congress' role. Without hearings or Congressional debate, the decision below was taken without an understanding of the significant effects the extension of Section 271(e)(1) would inevitably have on the medical device industry—effects different from those applicable to drugs.<sup>20</sup>

As noted, Title I of the 1984 Act allows the approval of generic copies of approved drugs on the basis of "bioequivalence" tests rather than the full safety and effectiveness trials otherwise necessary to justify FDA approval of a drug product. In a bioequivalence test, a generic drug manufacturer administers its generic copy and the innovator drug to a limited number of human subjects (who usually do not have the illness for which the drug is indicated)<sup>21</sup> to determine whether the rate and extent of absorption of its drug and of the innovator drug are equivalent. Cf. 21 U.S.C. § 355(j)(7) (definitions of bioavailability and bioequivalence). Upon submis-

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<sup>20</sup> The Federal Circuit not only acknowledged, but based its decision on, its inability to understand why Congress would treat drugs differently than medical devices in passing Section 271(e)(1). See *Eli Lilly*, 872 F.2d at 406 (quoted in Section II, *supra*).

<sup>21</sup> Test subjects who are ill will generally be used in bioequivalence tests only for drugs (such as cancer drugs) which are too toxic to be administered ethically to persons who will not receive a benefit from their use.

sion of test results showing bioequivalence, and data concerning the chemistry, manufacturing, and labeling of its drug, the generic drug manufacturer may obtain approval of either an ANDA submitted pursuant to 21 U.S.C. § 355(j) or a "paper" new drug application submitted pursuant to 21 U.S.C. § 355(b)(2).

The main effect of Section 271(e)(1) in the context of drugs is to allow the completion of such bioequivalency testing prior to expiration of the innovator patent. Although Section 271(e)(1) would allow nonbioequivalence testing of generic drugs if that testing were designed to obtain drug approval, the ordinary route to approval of a copy of a patented drug would be through bioequivalence testing, not through full clinical trials. Drug testing that would involve infringement of a drug patent but would not involve testing of a generic drug would be rare.

Congress found that bioequivalence testing of generic drugs has a *de minimis* effect on manufacturers of patented drugs. Since bioequivalence testing generally does not involve treatment of patients or permanent use of the product, bioequivalence testing does not take potential customers away from manufacturers of patented drugs during the life of the patent. Moreover, bioequivalence testing does not allow generic manufacturers to profit from copying a patented drug during the life of the patent because, as a practical matter, bioequivalence testing is never the subject of requests for reimbursement of the costs of treatment of test subjects. Therefore, despite Section 271(e)(1), manufacturers of patented drugs continue to enjoy exclusive sales during the life of the patent.

In fact, Congress specifically addressed the question of whether Section 271(e)(1) would result in a significant diminution of a drug patent owner's property rights in his or her patents. Congress concluded that Section 271(e)(1) was constitutional because it would have a *de minimis* economic impact on the holders of patents on

drugs. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 30 (1984):

In this case the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimus* [sic].<sup>22</sup>

See also H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 46 (1984).

By contrast, no process equivalent to bioequivalence testing exists for medical devices.<sup>23</sup> Nor is there any FDA approval process for medical devices that can fairly be called equivalent to either the ANDA or the paper new drug application processes described above for drug prod-

<sup>22</sup> See also *id.* at 8:

[T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.

As noted, bioequivalence is equivalence in the rate and extent of absorption of a drug. 21 U.S.C. § 355(j)(7)(B).

<sup>23</sup> In 1976, the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 540 (codified as amended at scattered sections of 21 U.S.C. § 301 *et seq.*), required premarket clearance, for the first time, for some medical devices. Because the definition of "device" covered a large category of products, ranging from tongue depressors to extremely sophisticated machinery, the statute provided for the division of medical devices into three classes. Class I devices were those that could be regulated without any type of premarket clearance or review by the FDA. Class II devices did not require premarket approval but were required to comply with performance standards should such performance standards be promulgated by the FDA. Class III devices required premarket approval. See 21 U.S.C. §§ 360c-360e. Medical devices on the market prior to 1976 and any device that could be shown to be "substantially equivalent" to such devices did not require premarket approval unless the FDA both classified them as Class III devices and required, by regulation, that such approval occur. See 21 U.S.C. §§ 360c(f), 360e(a)-(b).

ucts. If a device manufacturer wishes to make a "generic copy" of a device subject to the premarket approval requirement, the generic manufacturer must itself prepare all the safety and effectiveness data that will be necessary for approval of a premarket approval application for its generic copy. (Alternatively, it may petition FDA to "down-classify" the product, which could make the preparation of safety and effectiveness data unnecessary.)

Testing of medical devices also differs from testing of drugs. Many medical devices, in order to be tested to provide data to form a basis for approval, must be used in a treatment context. For example, hip replacements of the type produced by Zimmer must be implanted in patients in clinical trials of the devices. While such products are used investigational, they are also necessarily being used to treat the patients. A patient that receives a successful hip implantation during a clinical trial of a product made in violation of a patent will not later be available as a customer for the product of the patent holder.

Medical device companies may also recover their costs from investigational use of devices. Medical device regulations allow reimbursement for the costs of manufacturing, researching, developing, and handling a device while it is being tested. *See* 21 C.F.R. § 812.7(b) (1989). Companies thus commonly charge consumers and institutions for the experimental devices.

Moreover, the testing of a device may require not only its use in a therapeutic context but also its introduction to a significant part of the potential market for the device, a phenomenon not present in the drug context. For example, the sale of several expensive devices for which the number of potential customers is relatively small, such as the sale of diagnostic machines to hospitals, may satisfy the market demand for that device even prior to FDA approval. Of course, if it could be proven that a product was being used or sold for purposes other than

"for uses reasonably related to the development and submission of information under a Federal law," such use or sale would forfeit the protection of Section 271(e)(1). In many cases, however, perfectly legitimate use of a medical device investigational in an effort to develop necessary information to obtain approval of that device will result in both sale of the device, sometimes extensively, for therapeutic use in patients and the introduction of that device to and its sale to a substantial segment of the market.<sup>24</sup>

Therefore, if the Federal Circuit decision is allowed to stand, copiers of medical devices will be permitted to sell their copies, in the context of investigations, prior to the expiration of applicable patents. Thus, manufacturers of medical devices will not continue to enjoy exclusive sales during the life of their patents. Because investigational use of drugs, on the other hand, does *not* involve sales of competing products, Section 271(e)(1), interpreted in accord with its intent, does not abridge the right of a drug patent holder to exclusive sales during the life of its patent.

Because of these differences in the way drugs and medical devices are tested, the Federal Circuit's decision would significantly expand the reach of Section 271(e)(1). The decision whether such a rewriting of the statute is appropriate should be left to Congress.

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<sup>24</sup> Intraocular lenses are a good example of medical devices which are, to a great extent, marketed while investigational. Because of the rapid innovation in the intraocular lens field, it is not uncommon that, by the time a lens is approved, it is considered outdated.

**CONCLUSION**

For all the foregoing reasons, Zimmer respectfully requests this Court to reverse the Federal Circuit's decision.

Respectfully submitted,

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November 24, 1989